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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,788	01/16/2002	Xiang Yang Zheng	LIFE043	7478

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EXAMINER
WALLENHORST, MAUREEN

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 07/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/055,788	ZHENG ET AL.	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) *47-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-54* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-46, drawn to a control composition and a method of use in a coagulation test, classified in class 436, subclass 16.

II. Claims 47-54, drawn to a coagulation test device and kit having a container with multiple compartments therein, classified in class 422, subclass 102.

The inventions are distinct, each from the other because:

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process as claimed can be practiced by another and materially different apparatus such as a conventional test tube since the process does not require a container having two compartments therein in order to be performed. The search for Group I does not require a search for a container having two compartments therein.

2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

3. During a telephone conversation with Carol LaSalle on June 25, 2003, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-46. Affirmation of this election must be made by applicant in replying to this Office action. Claims 47-54 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 250 words. It is important that the abstract not exceed 250 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

6. The abstract of the disclosure is objected to because of the inclusion of legal phraseology such as "comprise" and "comprising". Correction is required. See MPEP § 608.01(b).

7. Claims 1-15, 19, 23 and 25-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On line 2 of claim 1, the phrase "capable of" is indefinite since a recitation than an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in a patentable sense. See this same problem on line 2 of claim 7, on lines 2-3 of claim 25, and on line 2 of claim 35.

In claim 5, the phrase "said calcium ion source" lacks antecedent basis.

In claim 15, the phrase "said aggregation enhancer" lacks antecedent basis since claim 15 depends from claim 7.

In claim 19, the phrase "said aggregation enhancer" lacks antecedent basis since claim 19 depends from claim 16.

On line 1 of claim 23, the phrase "said suspension" lacks antecedent basis.

Part c) of claim 25 is indefinite since it recites introducing the control composition and the plasma from step b) into a coagulation test. However, part b) of claim 25 recites that the control composition itself includes the plasma. Therefore, part c) of claim 25 should only recite that the control composition is introduced into the coagulation test.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-2, 4-7, 12-14, 16, 18, 20-22, 25-26, 32-36 and 43-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Coller.

Coller teaches of a composition for use in an agglutination/coagulation assay, wherein whole blood containing platelets with glycoprotein IIb/IIIa receptors is combined with polymeric beads coated with a glycoprotein IIb/IIIa ligand. When the platelets with unblocked receptors bind to the ligands on the beads, the beads coagulate. The composition comprises polymeric beads having charged functional groups thereon, such as carboxylated polystyrene beads. The beads may be combined with an optical contrast enhancer such as a dye so that they are colored to render the results of the agglutination reaction more visible and easier to interpret. In a coagulation test, a whole blood sample containing plasma therein is combined with the carboxylated polystyrene beads and a buffer containing calcium chloride. The coagulation of the beads in the blood is monitored as an indication of the degree that the glycoprotein IIb/IIIA receptors on the platelets are not blocked. If they are blocked, then no coagulation or agglutination of the beads occurs because there is no binding between the receptors on the platelets and the ligands on the beads. Therefore, Coller teaches of a composition comprising particles (i.e. polymeric beads) capable of aggregating in plasma, calcium ions (i.e. from calcium chloride) and plasma (i.e. found in whole blood).

11. Claims 1, 5, 7, 25-27, 29, 32, 35-37, 39 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Vogler et al.

Vogler et al teach of an additive for a blood collection container which comprises particles having a first surface region which activates clotting of blood, and a second surface region which adheres to blood clotting materials so that when a blood sample in the container clots and is centrifuged, the additive adheres to the clot and is removed from the serum layer. The particles can comprise surface modified polystyrene beads. In a coagulation time test, a

sample of platelet poor plasma is added to a blood collection tube containing the polystyrene beads, the sample is incubated for 15 minutes, and then calcium chloride is added to initiate clotting. The time of coagulation is monitored and noted for the test, and the coagulation time is compared to reference samples. See Example II in column 5 of Vogler et al. Therefore, Vogler et al teach of a composition comprising particles capable of aggregating in plasma (i.e. surface modified polystyrene beads), calcium ions (from calcium chloride) and plasma (from platelet poor plasma).

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 30-31, 40 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vogler et al. For a teaching of Vogler et al, see previous paragraphs in this Office action.

Vogler et al fail to teach of performing a prothrombin time test using the composition containing polystyrene beads. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to measure prothrombin time in the method of Vogler

et al since prothrombin time is a known, conventional coagulation/clotting time test, and Vogler et al teach of measuring coagulation time. In addition, it would have been obvious to one of ordinary skill in the art to determine a calibration curve for the clotting test taught by Vogler et al in order to determine the content of unknown blood samples based upon their coagulation time, and since the formation of calibration curves is conventional in the art of blood coagulation.

15. Claims 8-9, 17 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coller. For a teaching of Coller, see previous paragraphs in this Office action.

Coller fails to teach of an optical contrast enhancer in the solution of calcium ions. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to provide an optical contrast enhancer such as a dye in the solution of calcium ions taught by Coller since Coller teaches to include an optical contrast enhancer in the polymeric beads in order to make the results of the agglutination easier to read. The provision of the contrast enhancer in the calcium ion solution rather than the polymeric beads would achieve the same result when the calcium ions and beads are combined in the coagulation test.

16. Claims 3, 10, 15, 19 and 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coller in view of Lewis et al. For a teaching of Coller, see previous paragraphs in this Office action. Coller fails to teach of an aggregation enhancer in the composition.

Lewis et al teach that hemoglobin is an agglutination enhancer for synthetic particles such as latex. Therefore, based upon the combination of Coller and Lewis et al, it would have been obvious to one of ordinary skill in the art to provide the composition taught by Coller with an agglutination enhancer such as hemoglobin, as taught by Lewis et al, since the assay taught by Coller involves the agglutination of synthetic particles (i.e. polymeric beads).

17. Claims 11, 23 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coller in view of Jacobs et al. For a teaching of Coller, see previous paragraphs in this Office action. Coller fails to teach of an antifreeze in the composition used in the agglutination assay.

Jacobs et al teach of a hematology control composition that contains an antifreeze stabilizing agent therein to provide stability to the composition through freezing and thawing conditions. The stabilizing agent can be glycerol, ethylene glycol or propylene glycol. See lines 30-40 in column 4 of Jacobs et al.

Based upon the combination of Coller and Jacobs et al, it would have been obvious to one of ordinary skill in the art to provide the composition taught by Coller with one of the antifreeze stabilizing agents taught by Jacobs et al, so as to provide stability to the composition if it is subjected to freezing and thawing conditions.

18. Claims 28 and 38 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims since none of the prior art of record teaches or fairly suggests performing a coagulation test with the control composition recited in the instant claims, and comparing it to the same coagulation test performed on whole blood from which the plasma in the control composition originates.

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Vogler et al, Steel et al and Shaw et al who teach of different types of blood assays.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 703-308-3912. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is 703-305-7719.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

mmw

June 27, 2003

Maureen M. Wallenhorst

MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP [redacted] 1700